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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,437	02/06/2004	Kenneth J. Holroyd	0368070-5073-02	5555

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EXAMINER	
MERTZ, PREMA MARIA	

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,437	HOLROYD ET AL.	
	Examiner	Art Unit	
	Prema M. Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 37-61 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 37-61 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 37-44, 46, 48, 49, 5561, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering a chloride channel inhibitor to modulate the activity of ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, Class and subclass undeterminable.

Group II. Claims 37-44, 46, 47, 49, 55-61, drawn a method of treating a disease associated with ICACC protein activity by administering a chloride channel inhibitor to modulate the activity of ICACC-1 polypeptide of amino acid sequence set forth in SEQ ID NO:6, Class and subclass undeterminable.

Group III. Claims 37-44, 46, 48, 50, 55-61, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering an aminosterol to modulate the activity of ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, Class and subclass undeterminable.

Group IV. Claims 37-44, 46, 47, 50, 55-61, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering an aminosterol to modulate the activity of ICACC-1 polypeptide of amino acid sequence set forth in SEQ ID NO:6, Class and subclass undeterminable.

Group V. Claims 37-44, 46, 48, 51-53, 55-61, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering an antibody

to modulate the activity of ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 424, subclass 130.1.

Group VI. Claims 37-44, 46, 47, 51-53, 55-61, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering an antibody to modulate the activity of ICACC-1 polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 424, subclass 130.1.

Group VII. Claims 37-44, 46, 48, 54, 55-61, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering an antisense nucleic acid to the nucleic acid encoding ICACC-2 protein to down regulate the activity of an ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 44.

Group VIII. Claims 37-44, 46, 48, 54, 55-61, drawn a method of treating a disease associated with ICACC protein activity in the airways of a patient by administering an antisense nucleic acid to the nucleic acid encoding ICACC-1 protein to down regulate the activity of an ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 514, subclass 44.

Group IX. Claims 45, 46, 48-49, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering a chloride channel inhibitor to down regulate the activity of an ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, Class and subclass undeterminable.

Group X. Claims 45, 46, 47, 50, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering a chloride channel inhibitor to

down regulate the activity of an ICACC-1 polypeptide of amino acid sequence set forth in SEQ ID NO:6, Class and subclass undeterminable.

Group XI. Claims 45, 46, 48, 50, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering an aminosterol to down regulate the activity of an ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, Class and subclass undeterminable.

Group XII. Claims 45, 46, 47, 50, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering an aminosterol to down regulate the activity of an ICACC-1 polypeptide of amino acid sequence set forth in SEQ ID NO:6, Class and subclass undeterminable.

Group XIII. Claims 45, 46, 48, 51-53, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering an antibody to down regulate the activity of an ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 424, subclass 130.1.

Group XIV. Claims 45, 46, 47, 51-53, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering an antibody to down regulate the activity of an ICACC-1 polypeptide of amino acid sequence set forth in SEQ ID NO:6, classified in Class 424, subclass 130.1.

Group XV. Claims 45, 46, 48, 54, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering a antisense nucleic acid to the nucleic acid encoding ICACC-2 protein to down regulate the activity of an ICACC-2

polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 44.

Group XVI. Claims 45, 46, 47, 54, 55-61, drawn to a method of alleviating symptoms associated with inflammatory bowel disease by administering a antisense nucleic acid to the nucleic acid encoding ICACC-2 protein to down regulate the activity of an ICACC-2 polypeptide of amino acid sequence set forth in SEQ ID NO:4, classified in Class 514, subclass 44.

Should any one of the Groups from I-XVI be elected, Applicant is required to select one polypeptide (one amino acid sequence) as set forth in SEQ ID NO:4 or 6. Once one polypeptide sequence is selected, the other sequence will be withdrawn from consideration.

Furthermore, Applicants are requested to correct the dependency of claim 54, which is dependent on canceled claim 1, and to correct the dependency of claims 49-50 to depend from specific claims i.e. claims 37 to 45.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-XVI are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials, process steps and goals. Furthermore, separate search terms would be required for searching the literature, eg. a search of the literature for an association of a chloride channel inhibitor with cystic fibrosis would not necessarily reveal art for an association of an aminosterol with cystic fibrosis.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. j 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Election of species

2. This application contains claims directed to the following patentably distinct species of disease the claimed invention:

If either Groups I-VIII are selected, Applicants are required to elect one of the following species of disease, selected from:

(a) cystic fibrosis;

(b) bronchial hyperresponsiveness;

© decrease in inflammatory cells; and

(d) improvement in pulmonary function.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of disease for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37-39, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. This application contains claims directed to the following patentably distinct species of cells of the claimed invention:

If either Groups I-VIII are selected, Applicants are required to elect one of the following species of cells, selected from:

(a) mast cells;

(b) eosinophils;

© lymphocytes; and

(d) epithelial cells.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of cells for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37-39, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. This application contains claims directed to the following patentably distinct species of modes of administration of the claimed invention:

If either Groups I-XVI are selected, Applicants are required to elect one of the following species of modes of administration, selected from:

(a) inhalation;

(b) parenterally; and

© intravenously.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of modes of administration for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 37-39, 44-45, are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D., J.D.
Primary Examiner
Art Unit 1646
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